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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/370,453	08/09/1999	DAN W. DENNEY JR.	GENITOPE-038	8128
23535	7590	06/02/2004	EXAMINER	
MEDLEN & CARROLL, LLP 101 HOWARD STREET SUITE 350 SAN FRANCISCO, CA 94105			YAEN, CHRISTOPHER H	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/370,453

Applicant(s)

DENNEY, DAN W.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6 and 25-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6 and 25-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/26/2004.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Re: Denney D.

Priority Date: 01 May 1996

1. The amendment filed 2/26/2004 is acknowledged and entered into the record.

Accordingly, claims 2, and 7-24 are canceled without prejudice or disclaimer.

2. Claims 1,3-6, and 25-32 are pending and examined on the merits.

Information Disclosure Statement

3. The Information Disclosure Statement filed 2/26/2004 is acknowledged and considered. A signed copy of the IDS is attached hereto. Reference #3 (EP 0307285A1) was not considered because the reference is in a foreign language and no officially translated copy was provided. Furthermore, applicant has not provided an explanation of its relevance to the instant application.

Claim Rejections Maintained - 35 USC § 102

4. The rejection of claims 1,3-6, and 25-32 under 35 USC 102(b) as being anticipated by Chen TT *et al* is maintained for the reasons of record. Applicant argues that a single immunoglobulin molecule comprises a "single set" of idiotypes and therefore different variable regions (i.e., a single VH and a single VL) from within a single immunoglobulin molecule cannot be "from immunoglobulin molecules that differ by at least one idiotope" (see paper filed 2/26/2004, page 8). Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. An idiotype is defined as regions determined by idiotopes (see

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www.hyperdictionary.com), whereas an idiotope is defined as antigenic peptide sequences that are located within the antibody variable region (see www.hyperdictionary.com). Moreover, the specification defines an idiotype as “a set of antigenic or epitopic determinants (i.e. idiotopes) of an immunoglobulin variable domain”, whereas idiotopes are defined as a single set of idiotypic epitopes located on the V region of an antibody (see page 22, lines 9-13). Therefore, it is clear that because idiotopes make up idiotypes of an antibody, and because idiotopes are, in its simplest form, an antigenic epitope located within the variable domain of an antibody, light chains and heavy chains would have different idiotopes because they are structurally different molecules encoded by different amino acid sequences.

Applicant also argues that the claims are drawn to a molecule that comprises “at least two recombinant protein molecules comprising variable regions of at least two immunoglobulin molecules” (see paper filed 2/26/2004 bridging pages 8-9), and therefore are derived from at least two distinct immunoglobulins. Applicant’s arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. The specification on page 22, lines 3-8 defines an immunoglobulin as a molecule that consists of heavy chain (H) and light (L) chains. This however does not preclude an immunoglobulin molecule from being a single heavy and a single light chain only (i.e. single chain Fv). Because the claims are to be read with the broadest reasonable interpretation, the claims are read to the extent that “at least two immunoglobulin molecules” is a single heavy and single light chain, it does not preclude or limit the immunoglobulin molecules to be derived from different immunoglobulin

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molecules. Therefore, the molecule taught by Chen TT *et al* fulfills the limitation of at least two immunoglobulin molecules because an antibody molecule comprises a set of heavy chains and light chains (i.e. a least two immunoglobulin molecules), and as set forth above, the idiotopes from a light chain would differ from idiotopes from a heavy chain.

Therefore the prior art rejection under 35 USC 102(b) is maintained.

Conclusion

5. **No claim is allowed.**

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
May 26, 2004



GARY NICKOL
PRIMARY EXAMINER